No. 88-1446

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JOSEPH F. SPANIOL, JR.
CLERK

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1988

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NEW YORK STATE OPHTHALMOLOGICAL SOCIETY, CALIFORNIA ASSOCIATION OF OPHTHALMOLOGY, *et al.*,
*Petitioners,*

v.

LOUIS W. SULLIVAN, Secretary,
United States Department of Health
and Human Services,
*Respondent.*

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

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## REPLY BRIEF OF PETITIONERS

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## REPLY BRIEF OF PETITIONERS

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The statute at issue in this case, § 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985, 42 U.S.C. § 1395u(k), takes away patients' ability to choose, in conjunction with a qualified physician, a course of medical treatment which the government itself acknowledges is medically preferable and which is indisputably not harmful.[1] The majority opinion below held that

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[1] "Defendant does not deny that the attendance of an assistant specialist may be *preferable* in *any* [cataract] operation or that adverse medical consequences may otherwise result . . . ." Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, p. 22 (emphasis supplied).

this deprivation does not implicate any constitutionally cognizable interests—and therefore does not require any balancing of governmental interests against patient interests—unless the treatment involved is proved "indispensable to a patient's life, health or sight." (Pet. App. 17a). This holding constitutes an unprecedented diminution of interests in personal security protected substantively by the Due Process Clause. Moreover, it conflicts with this Court's consistent recognition of those interests.

Significantly, respondent's effort to dissuade this Court from hearing this case is not premised on a different understanding of the impact of the statute on patient interests in medical decision-making and safety. Indeed, respondent himself frames the question presented as, "Whether Section 9307(c)(2) is unconstitutional on its face because it deprives patients of their right to choose medical treatment." Brief for the Respondent in Opposition ("Opp.") at (I). Respondent argues, however, that these patient interests—in diminishing risks to eyesight—are simply not of constitutional significance. It relies on the majority's extraordinarily cramped and erroneous view of the scope of patient interests entitled to constitutional consideration. This case thus squarely poses questions of the utmost importance regarding whether patients possess a constitutional interest in choosing a safer course of medical treatment and whether the strength of the government's reasons for restricting such a choice are of relevance and must be weighed. For the reasons set forth below and in the Petition, this case should be heard by this Court.

1. Contrary to respondent's first argument, this case is ripe for review. The challenged statute precludes Medicare patients from hiring a cataract surgical assistant ("CAS") without prior approval by a governmentally designated organization "based on the existence of a complicating medical condition." 42 U.S.C. § 1395y(a)(15). Petitioners, however, want to receive or provide

CAS services even in the absence of "a complicating medical condition." Their contention, as described by the court of appeals, is that "every patient, regardless of pre-existing risk factors, is exposed to a significantly greater chance of unforeseen, dangerous complications without a second surgeon" (Pet. App. 18a), because unpredictable emergency complications necessitating CAS services occur in approximately 3% of cataract surgeries. *See* Petition at 4-5 and n.2. In short, petitioners attack the appropriateness of the "complicating medical condition" standard at the outset because, as even the government has recognized (*see* Petition at 12), CAS services contribute in all cases to the incremental margin of safety—not merely in those cases where a complicating condition may exist.

As the majority opinion correctly noted, "How the PROs apply the guidelines concerning 'complicating medical conditions' or other factors that entitle patients to approval does not bear on whether the PROs should be making this inquiry in the first place." (Pet. App. 14a). Petitioners object to this medically inappropriate inquiry and to any resulting restriction on the provision of CAS services. It is therefore irrelevant to the ripeness of petitioners' claims that they have not gone through the approval process because the approval process itself is the subject of petitioners' objections. *Compare Doe* v. *Bolton*, 410 U.S. 179 (1973) (permitting challenge to statute by physicians whose patients had not yet applied to hospital committee for abortion approval or sought two-physician concurrence). Indeed, it would be utterly pointless to require petitioners to submit applications for approval articulating the medical view that *all* cataract surgies are inherently safer if accompanied by CAS services when the statute by its terms prohibits approval on such a basis. Unless the statute is to be rendered a nullity, universal approval will not be forthcoming.

The majority opinion recognized this reality, recognized that most applications for approval will be denied (Pet.

App. 16a), and proceeded to render a decision on the merits of petitioners' facial challenge. The impact of that erroneous decision on the merits cannot now be avoided by respondent's fallacious ripeness argument. Accordingly, the merits of this case are ripe for review by this Court.[2]

2. The majority below acknowledged that "the type of burden imposed on patients by this scheme . . . would not withstand scrutiny in the context of a recognized constitutional interest." (Pet. App. 9a). It held that patients have no "recognized constitutional interest" in choosing a safer medical procedure, however, unless the "treatment [is] indispensable to a patient's life, health or sight . . . ." (Pet. App. 17a; *see also* Pet. App. 24a-26a). Due to this holding, the majority did not address the nature or strength of the governmental interests alleged to justify § 9307(c) and did not weigh those interests against those of patients.

Respondent seeks to minimize the significance and extreme nature of this holding by claiming that the majority opinion did not actually describe the "circumstances in which an individual's interest in health-related matters would be entitled to some weight in constitutional analysis." (Opp. at 6). This revisionist interpretation fails to account for the majority's failure to balance the competing interests. Further, it is flatly contradicted by the majority opinion itself. In disposing of what it characterized as petitioners' "liberty" claims, the majority

[2] While deciding what it characterized as petitioners' "privacy" claim, the majority below also held that petitioners' "liberty" claim was not ripe, as respondent accurately notes. But as explained in our Petition, p. 10, this limited procedural holding was wholly derived from the majority's decision on the merits that only "indispensable" medical treatment rises to the level of a "legally cognizable" liberty interest. Respondent does not dispute this fact. "Ripeness" can hardly be a reason for avoiding review of the merits, however, when the "ripeness" determination itself rests on the same decision on the merits that is being challenged.

explicitly stated that any such claim would require "*at a minimum*" a showing "that the challenged regulation restricts access to treatment indispensable to a patient's life, health, or sight in a way that 'shocks the conscience.'" (Pet. App. 17a) (emphasis supplied). Similarly, in deciding petitioners' "privacy" claims the majority held that "*the prerequisite* to a successful privacy claim would be a definite showing of medical necessity." (Pet. App. 24a) (emphasis supplied). In sum, the majority *did* set a base-line test under which no constitutional weight attaches to patient interests in choosing a safer medical treatment except in extreme medical circumstances.

As explained in our Petition at 14-21, this Court's decisions squarely conflict with such an approach. In every case in which this Court has been confronted with a governmental action that directly threatens to impose a risk to an individual's health, even a slight or uncertain risk, this Court has recognized that important constitutional interests in personal security are implicated. *See, e.g., Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U.S. 747, 768-69 (1986); *Winston* v. *Lee*, 470 U.S. 753, 767 (1985). Indeed, respondent is unable to cite any authority of this Court even suggestive of a contrary view, or supportive of the notion that no weighing of competing interests is necessary in such a circumstance.

Instead, respondent resorts to noting that the facts involved in these prior cases differ from those involved here. Opp. at 5-6. This is indisputable. In fact, § 9307 (c) is "unprecedented" (Petition at 12). Never to our knowledge has any governmental body sought to preclude private patient access to a medical procedure conceded to be medically "preferable." *See* p. 1, n.1, *supra*.

But while this case differs factually from those previously considered by this Court, there is no principled basis for distinguishing the patient interests at stake

here from the constitutional patient interests recognized by this Court in other settings. For example, it is true that *Youngberg* v. *Romeo*, 457 U.S. 307 (1982), concerned treatment of a mentally retarded individual in a state institution. Opp. at 5. But the historic "right to personal security" (*id.* at 315) recognized in that case, including a right to be free from endangering governmental actions, does not apply only to confined individuals. The "liberty" interests of the free populace are at least equal and are implicated by governmental action that prevents an individual from taking private steps to ensure health and safety, *i.e.*, in this case eyesight.[3]

Respondent's attempted distinction of *Winston* v. *Lee*, 470 U.S. 753 (1985), is similarly unavailing. That case involved a governmentally *compelled* medical procedure creating risks to health while this case involves a governmental *prohibition* on medical procedures that creates risks to health. In both cases, however, it is the patient's interest in preserving health and safety that is threatened, and it is governmental action that creates the threat. The fact that the form of the governmental action differs is irrelevant. *See* Petition at 16. Respondent has not replied to this analysis or suggested any principled basis for distinguishing between the two cases.

Respondent also attempts to distinguish *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986), and the related cases discussed in the Petition at 16-18 and n.11, by reiterating the claim of the court of appeals majority that the protections afforded in *Thornburgh* are merely "a means to the end of free reproductive self-determination or autonomy." Opp. at 6. That

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[3] *See DeShaney* v. *Winnebago County Department of Social Services*, —— U.S. ——, 57 U.S.L.W. 4218, 4221 (1989) ("In the substantive due process analysis, it is the State's affirmative act of restraining the individual's freedom to act on his own behalf . . . which is the 'deprivation of liberty' triggering the protection of the Due Process Clause . . . .")

claim is simply wrong, however, as explained at length in the Petition at 16-18. *Thornburgh* dealt with a statute regulating medical techniques used in *post*-viability abortions. In the *post*-viability stage, a woman's interest in "free reproductive self-determination" is not protected, but her interest in preserving her health and life is. Accordingly, this Court's refusal to allow any *post*-viability "trade-off" that would require the woman to bear an increased medical risk is attributable to the protection of the woman's health interests, not to the end of free reproductive self-determination. Respondent simply ignores this analysis while offering none in its stead.

These cases are reflective of an unbroken chain of precedents, both in this Court and the lower courts, which have treated governmental infringements on patients' health and safety interests with the utmost seriousness. This is not to say that "any governmental interference with a person's choice of medical treatment" is "subject to strict scrutiny."[4] Opp. at 5. Rather, it suggests that a weighing of interests is appropriate, and that the nature of the interest asserted by the government is critical in this balancing.

It is one thing for the government to interfere with a medical choice in order to protect patient or community health. *See* Petition at 13, n.8, and 19-20. It is quite another thing for the government to interfere with a medical choice not to protect health but rather to prevent individuals from "unwisely" spending personal funds to lessen health risks (Pet. App. 33a)—especially where its intervention concededly increases risks to a patient's health. That is what the government has done here. The

[4] Although respondent also raises abstract concerns about what constitutes a "medical decision" (Opp. at 5), these concerns have no bearing on this case or its appropriateness for review. Petitioners here seek protection to choose a specific class of surgical services which are unquestionably medical in nature, and which bear directly on the extent of health risks in surgery.

majority below fundamentally erred by not treating such governmental action as implicating constitutional interests and therefore failing even to consider whether the government interests asserted are significant enough to justify the resulting threat to patient health.

3. This case presents an issue of national importance. It is no less important because the issue has not been adjudicated by another circuit. For the one million senior citizens who undergo cataract surgery annually and who are exposed to an increased risk of loss of an eye or other serious injury by § 9307(c), review of this matter cannot further be delayed.

## CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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